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1 77CVPURC Conference
1 UNITED STATES DISTRICT COURT
1 SOUTHERN DISTRICT OF NEW YORK
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3 PURDUE PHARMA, L.P. AND PF
3 LABORATORIES INC.,
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4 Plaintiffs,
5 v. 07 CV 03972 (SHS)
5 07 CV 03973 (SHS)
6 07 CV 04810 (SHS)
6 KV PHARMACEUTICAL CO. AND
7 ACTAVIS TOTOWA L.L.C.,
7
8 Defendants.
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10 PURDUE PHARMA L.P., ET AL,
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11 Plaintiffs,
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12 v. 06 CV 13095 (SHS)
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13 MALLINCKRODT INC.,
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14 Defendant.
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15 -----x
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16 New York, N.Y.
16 July 12, 2007
17 3:25 p.m.
17
18 Before:
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19 HON. SIDNEY H. STEIN,
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20 District Judge
20
21 APPEARANCES
21
22 ROPES & GRAY
22 Attorneys for Plaintiffs on 07 CV 3972
23 BY: ROBERT J. GOLDMAN
23 PABLO D. HENDLER
24 RICHARD A. INZ
24
25
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1 APPEARANCES (cont'd.)
2 JONES DAY
2 Attorneys for Plaintiffs on 06 CV 13095
3 BY: JOHN J. NORMILE
3
4 MORGAN & FINNEGAN
4 Attorneys for Defendants KV Pharmaceutical Co.
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5 BY: JOHN F. SWEENEY
5 SETH J. ATLAS
6 -AND-
6 SKADDEN ARPS SLATE MEAGHER & FLOM
7 BY: STEVEN C. SUNSHINE
7
8 AXINN VELTROP & HARKRIDER
8 Attorneys for Defendants Actavis Totowa L.L.C.
9 BY: CHAD A. LANDMON
9 MARK D. ALEXANDER
10
10 LORD BISSELL & BROOK
11 Attorneys for Defendant Mallinckrodt Inc.
11 BY: HUGH L. MOORE
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1 Conference
2 (In open court)
2 (Case called)
3 THE DEPUTY CLERK: Purdue against KV, 07 CV 3972; and
4 Purdue against Mallinckrodt, 06 CV 13095.
5 Counsel, please state your names for the record.
6 MR. GOLDMAN: Good afternoon, your Honor. Robert
7 Goldman, Ropes & Gray, for Purdue in the KV and Actavis cases.
8 And with me are my colleagues Pablo Hendler and Richard Inz.
9 THE COURT: Good afternoon.
10 MR. NORMILE: Good afternoon, your Honor. John
11 Normile, Jones Day Law Firm, on behalf of Purdue Pharma and the
12 other Purdue plaintiffs in Purdue v. Mallinckrodt, 06 CV 13095.
13 THE COURT: Good afternoon. Please be seated.
14 MR. LANDMON: Good afternoon, your Honor. I'm Chad
15 Landmon with Axinn, Veltrop & Harkrider on behalf of Actavis.
16 With me today is Mark Alexander.
17 THE COURT: Good afternoon.
18 MR. SWEENEY: Good afternoon, your Honor. John
19 Sweeney of Morgan & Finnegan for KV. And with me today is my
20 partner Seth Atlas.
21 MR. SUNSHINE: Good afternoon, your Honor. Steve
22 Sunshine from Skadden Arps representing KV with respect to
23 antitrust issues.
24 MR. MOORE: Hugh Moore from Lord, Bissell & Brook
25 representing Mallinckrodt.

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1 THE COURT: 06 CV 13095.
 2 MR. MOORE: That's correct, your Honor.
 3 THE COURT: Good afternoon to all of you. We're
 4 actually here, just so the record is clear, on the three KV
 5 cases: 07 CV 3972, 07 CV 3973, and 07 CV 4810; as well as we
 6 recently folded in the Mallinckrodt case of 06 CV 13095 based
 7 on the correspondence and my direction to have Mallinckrodt
 8 here today.

9 The information that I think is relevant for this
 10 conference is, of course, the order of the Federal Circuit
 11 dated February 1, 2006, and the Rule 26(f) submission of the
 12 parties of KV, the three KV cases, dated June 13; plus the
 13 follow-up letters of Morgan & Finnegan on the 14th, Ropes &
 14 Gray on the 18th, and Axinn Veltrop of June 22, all telling me
 15 what that Rule 26(f) report said.

16 And then we simply have the two pieces of
 17 correspondence in regard to folding in Mallinckrodt, and that's
 18 the letter of Jones Day dated July 6, and the letter of Lord
 19 Bissell dated July 9. That's the basis of what we're going to
 20 discuss today.

21 Let me give you an overview of where I stand and what
 22 I think we have to do. I won't put too fine a point on it
 23 because I want to hear the positions of the parties, as well.

24 It seems to me that the issue in this case for the
 25 past several years, it is the remand of inequitable conduct, in

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1 my determination, as to whether or not there was inequitable
 2 conduct such that the patent here was invalidated. That's
 3 really what the Federal Circuit remanded for me to do back in
 4 February. We had a way of proceeding. I was going to decide
 5 that issue on remand based on the Endo record. The parties'
 6 relevant litigations had agreed on that. But events have
 7 passed that by. We're in a different situation now, given the
 8 public settlement of some of these cases and new litigation
 9 specifically, obviously, the two KV cases that were started in
 10 Delaware, 3972 and 4973, and the one that was started here,
 11 4810. And the fact of the Mallinckrodt suit.

12 But what underlies all of those is there needs to be a
 13 determination on whether inequitable conduct has invalidated
 14 the patent. The antitrust issues I said in the MDL and stated
 15 in the MDL, I think don't have to necessarily follow a
 16 determination of inequitable conduct.

17 Now, there's some discussion in these papers about
 18 there being an overlap in discovery, and I'm not quite sure
 19 that that's so. But whether or not there is, I think
 20 conceptually the antitrust counterclaim should just be put off
 21 to another day until after the invalidity is decided. When I
 22 say "invalidity," I mean invalidity and unenforceability. So
 23 if we're talking big picture, I think that's really element 1
 24 in my thinking. The antitrust counterclaim is for another day.

25 I guess big picture item No. 2, part of that, is I'm
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1 under statutory obligation here to move these HatchWaxman
 2 cases. And the parties are under a statutory obligation to
 3 coordinate in attempting to expedite the matter. Now, that's
 4 hard to believe, given the long history here and the amount of
 5 effort that's been put in in part by me, but more importantly,

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6 by the scores of lawyers who have been involved in these cases
 7 going back to Endo. It's been a long time since they've
 8 started. And I think it's simply time to bring them to a head.
 9 And the way to do that, I think, is to effectuate the mandate
 10 of the Federal Circuit.

11 Now, conceptually, the easiest way for me to handle
 12 that is on the Endo record. There's some defendants here, I
 13 think that would be unfair. And to the extent they are raising
 14 issues of invalidity and unenforceability that were not part of
 15 the Endo record, I guess I want to hear about that. Because to
 16 the extent that that's true, their points have some
 17 credibility; that is, why should I go forward on the Endo
 18 record if they don't have opportunity to develop their
 19 counterclaims on invalidity and inequitable conduct to the
 20 extent they're non-Endo issues. But I don't have a good sense
 21 of that from the papers. If there are such issues, well, I
 22 think those parties should be able to develop it, all within
 23 the bigger context of gentlemen, let's get this done.

24 The timetables set forth in the proposal I think range
 25 from being too long to being very too long. But I don't think

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1 that that's inconsistent with the desires of the parties. And
 2 assuming everyone agrees with me, or at least is prepared to
 3 live with my relatively strong feeling that the antitrust
 4 counterclaims are just not going to be handled now, it doesn't
 5 make sense in terms of judicial efficiency.

6 Now, you'll realize I haven't said a word about
 7 infringement. I'm not really sure where infringement plays in
 8 terms of a violation of Actavis has conceded infringement. I
 9 don't know if KV has weighed in on infringement or not yet.

10 MR. SWEENEY: No, your Honor, we have not conceded
 11 infringement. And we anticipate making a noninfringement
 12 argument.

13 THE COURT: All right. But in an odd way,
 14 infringement also, perhaps like the antitrust counterclaims,
 15 seems to me to be an issue for another day, at least insofar as
 16 infringement was found and upheld; that is, found by me and
 17 upheld by the Federal Circuit in Endo. And we have a session
 18 of infringement by Actavis.

19 I don't think conceptually the issue of infringement
 20 is going to try these litigations; obviously, it's an important
 21 issue. But the most important one, I think, is invalidity and
 22 unenforceability. If invalidity is found, then infringement
 23 drops out.

24 MR. SWEENEY: Yes, your Honor, just to follow up what
 25 I said. We're fine with going forward with the inequitable

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1 conduct issue first. KV would not be seeking discovery beyond
 2 the Endo record. However, I just want to make it clear that we
 3 will and do have a noninfringement position if we get to that
 4 day.

5 THE COURT: Okay. Nobody's waiving anything. We're
 6 trying to figure out where we're going. I understand that,
 7 Mr. Sweeney. That's another point that I thought of I should
 8 make. It sounds like Mr. Sweeney at least is not disagreeing
 9 with me, that it is in an odd way infringement itself takes a
 10 back seat here to invalidity and unenforceability.

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11 To the extent I have agreement on all that, what we're
 12 doing is really narrowing and focusing this case between
 13 invalidity and unenforceability, putting everything off because
 14 it may not need to be addressed depending upon what happens in
 15 the invalidity and unenforceability determination.

16 I need a better sense of what discovery, if any, is
 17 necessary on that issue, given the Endo record. There clearly
 18 will be a dump, if you will, of the prior litigation documents
 19 by Purdue; I think that's foreseen in all of your statements
 20 here, which gets everybody a good way there.

21 That's how I see it. And I see it all happening this
 22 year. Who would like to tell me whatever they'd like to tell
 23 me?

24 MR. GOLDMAN: Your Honor, if we were starting on a
 25 clean slate, Purdue's position would be as it was back in
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 1 December: It impacts that we ought to prepare discover and try
 2 all the issues together, because that would be, from Purdue's
 3 point of view, the most expeditious way to do it. But we
 4 understand the logic of what your Honor wants to do. And I
 5 think we're past the point now of trying to proceed in that
 6 fashion.

7 what has been the experience on the remand briefing to
 8 date is that there are the remand issues, and then there are
 9 additional issues; that is, the issue that was addressed in the
 10 Federal Circuit opinion and in your opinion in Endo were issues
 11 relating to the question of the statements about the 10-40
 12 milligram dosage range and so on and so forth.

13 THE COURT: And the existence of test results.

14 MR. GOLDMAN: That's right.

15 THE COURT: Okay.

16 MR. GOLDMAN: And the remand dealt with a
 17 particular -- essentially affirmed your Honor on the question
 18 of materiality, characterized the materiality as low, and said
 19 that the facts upon which your Honor based your inference of
 20 intent were not sufficient to support the inference based on
 21 the Federal Circuit's characterization of materiality.

22 THE COURT: I think that's a fair characterization.

23 MR. GOLDMAN: On remand in Endo and on the remand
 24 briefing in Impax and Boehringer, both all of the defendants
 25 have attacked the problem by bringing in issues that Purdue

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 1 believes were not tried in the Endo case. Maybe you can find
 2 support for pieces of them in the Endo record, but essentially
 3 they weren't tried; they were new issues.

4 And so if there were a way to focus the so-called
 5 remand briefing on the issues simply raised by the remand,
 6 Purdue would have no problem with that.

7 THE COURT: Purdue would have no problem with --
 8 MR. GOLDMAN: With proceeding with briefing the
 9 so-called Endo remand.

10 THE COURT: Right. But the fly in that particular
 11 ointment is new cases KV and Mallinckrodt. And perhaps there
 12 are counterclaims here regarding inequitable conduct that were
 13 not raised in Endo; although it's a little hard for me to
 14 determine that from the bare pleadings that I have.

15 MR. GOLDMAN: Understood. And so the question that we

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16 then have to address is how do we sort out that which is new
 17 from that which is essentially the remand issue. And perhaps
 18 the Court has thought about it. We're sort of wrestling with
 19 the issue trying to come up with a proposal.

20 One way to do it would be to simply brief the
 21 inequitable conduct issue, whatever anybody wants to say about
 22 it; and at the same time, Purdue would brief the question of
 23 what we believe is new that is in response to the briefs that
 24 we received from the defendants. And then at the conclusion of
 25 the briefing, we would come to see your Honor for a status

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 1 conference, at which the Court could determine how it wanted to
 2 proceed on the so-called new issues; that is, it may be that we
 3 have to have a hearing of half -- it may be simply that the
 4 record gets supplemented, as Purdue moved to do in each of the
 5 Endo and Impax situations, and Boehringer agreed to do in the
 6 last round.

7 It may be that we need to have an evidentiary hearing
 8 on those new issues that will take half a day or a day. But it
 9 seems to me that if the Court wants to brief the inequitable
 10 conduct issue first, and we can't figure out a way to limit it
 11 just to what's on the remand, then we have to lay it all out,
 12 try to determine in that process what's new, and then come see
 13 your Honor and ask whether the Court wants to just hear
 14 argument, will accept an offer of proof, or wants to have an
 15 evidentiary hearing on the rest of the issues.

16 That's Purdue's proposal as best we can crystallize it
 17 at this point.

18 THE COURT: Unless I miss my mark, and I don't want to
 19 encourage the unnecessary discovery proceedings, I would assume
 20 KV, Actavis, and Mallinckrodt are going to say we want
 21 discovery on what we claim is leading to the invalidity and the
 22 unenforceability; that is, separate and apart from the Endo
 23 issues, because I'm not going to allow re-discovery on that.
 24 Don't you think that's what's in these papers? It's not even
 25 lurking in the paper, it's right there.

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1 MR. GOLDMAN: It's right there. If the Court is
 2 inclined to allow discovery to reopen, it seems to us that
 3 discovery ought to reopen on all of the invalidity issues, as
 4 well as in addition to inequitable conduct.

5 THE COURT: You mean on everything that was discovered
 6 and briefed in Endo?

7 MR. GOLDMAN: I don't know how much discovery the
 8 defendants will need on any of the issues that were discovered
 9 in Endo. They'll tell you. But Purdue is entitled to
 10 discovery from each of the defendants as to how their products
 11 came to be developed and how they came to be, particularly in
 12 light of the recent decision from the Supreme Court, which sort
 13 of broadens the scope of the evidence that's relevant on the
 14 inquiry into obviousness. And so that would be the discovery
 15 that Purdue would wish. Purdue would like to take discovery of
 16 the defendants with respect to how their products came to be.

17 THE COURT: How is that relevant to their
 18 counterclaims of invalidity and unenforceability?

19 MR. GOLDMAN: It's relevant to the counterclaims of
 20 invalidity, not unenforceability. It's relevant to the

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21 counterclaims of invalidity insofar as it bears on how people
 22 of ordinary skill in the art dealt with the art and thought
 23 about the art and looked at the art internally in terms of
 24 resolving the issue of obviousness with respect to which is one
 25 of the invalidity issues.

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I agree, on the issue of inequitable conduct, it's not. What's relevant is what happened at Purdue and what happened between Purdue and the patent office. But invalidity goes broader than that.

THE COURT: The issue for me is whether or not that discovery can be contained sufficient to allow this to go forward and be done in the next couple of months.

MR. GOLDMAN: I believe that there's no reason we can't at least brief the remand issues now or get on some schedule to brief the remand issues.

THE COURT: Those are essentially done -- or that's essentially done, right?

MR. GOLDMAN: I'm not sure I understand what you mean by "essentially done," your Honor.

THE COURT: I had briefing in that and some other cases already that were sitting around when events moved beyond that.

MR. GOLDMAN: I believe that's right. Although I think you'd have to ask counsel for the defendants, to the extent in which they are ready to embrace the briefs filed by other counsel.

But we can do the briefing on the remand issue promptly. At the same time, discovery can go forward on all the other issues with the anticipation that we're going to have to go discover and try those issues someday.

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THE COURT: Again, I go back. I don't really know what they're claiming in terms of invalidity and unenforceability. That's different from Endo. But if they are claiming things that are different, aren't they entitled to some discovery on that before there's a determination of those issues by me?

MR. GOLDMAN: If they're entitled to discovery on the invalidity issues, your Honor, then I believe Purdue is entitled to discovery on them also. That's really the problem with trying to -- not to contain it, but simply to -- the question your Honor is asking is how quickly can we get this done so we can get to the briefing on the issue that remains. And I guess what I'm trying to suggest is that on the remand issue itself, we can do that promptly.

And to the extent that one gets into the new issues of inequitable conduct, the new arguments of inequitable conduct, I don't see a way for that -- that's going to take longer, one way or the other; either because Purdue will want to supplement the record because the defendants will want to take some discovery. It's just going to take a little bit of time. How much time, I can't say, because I also don't quite understand what defendants have that's new.

THE COURT: There may not be anything. I'm going to ask them and we'll see.

MR. GOLDMAN: Yes.

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1 THE COURT: But what's the point of deciding the
 2 remand issue that is based on the Endo record if I'm going to
 3 have to recalculate that analysis for subsequent information,
 4 assuming there are new things? There's no point in doing that.

5 MR. GOLDMAN: I agree with you, your Honor. But you
 6 began with the proposition that you start with the remand order
 7 and how do I resolve that.

8 THE COURT: Okay.

9 MR. GOLDMAN: And I was trying to respond to that.

10 THE COURT: Okay. I understand. Thank you. All
 11 right. Let me hear from the defendants. Mr. Sweeney.

12 MR. SWEENEY: Your Honor, yes. Our position is we
 13 would like to go ahead with the remanded inequitable conduct
 14 brief, because we think that it is potentially quite
 15 dispositive. This Court has found inequitable conduct before;
 16 the Federal Circuit has affirmed the withholding of material
 17 information; and there is evidence of inequitable conduct,
 18 intent to deceive, beyond what the Federal Circuit considered
 19 that can be submitted here on remand. And we're not seeking
 20 any further discovery at this stage. So we're a little
 21 different from the other two defendants in that respect, I
 22 believe.

23 THE COURT: Just a moment.

24 (Pause)

25 THE COURT: Yes, sir.

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1 MR. SWEENEY: Now, I think it is correct to separate
 2 inequitable conduct, which relates to enforceability, and
 3 validity or invalidity. What was remanded, I think Mr. Goldman
 4 is correct is the issue of inequitable conduct, and that's what
 5 we would intend to brief.

6 Now, the Endo record does have evidence in it of
 7 invalidity, as well. For instance, the examiner found the
 8 claims obvious, and he didn't change that until he thought he
 9 got data. And so even if there's not an intent to deceive in
 10 withholding data, it would be our argument that you would
 11 revert to this determination that the examiner made, which is
 12 obvious, since that has nothing to do with the remanded issue
 13 per se; that's invalidity.

14 And I think that, like infringement or
 15 noninfringement, the way to a later day, I think the urgency
 16 here with the inequitable conduct is there has been a mandate
 17 from the Federal Circuit and a remand on this specific issue;
 18 briefs have been submitted in prior litigations; and we would
 19 like to submit our brief on that issue, as well. And then
 20 hopefully that will be dispositive. If it's not though, then
 21 there can be two-way discovery on the other validity issues,
 22 the discovery that Mr. Goldman wants and the discovery that the
 23 other defendants want, and we can get to the questions of
 24 obviousness and other validity issues, along with infringement
 25 issues.

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1 THE COURT: And I take it, Mr. Goldman, that's
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2 consistent with your interests, as well, the way Mr. Sweeney
3 has phrased it.

4 MR. GOLDMAN: It would certainly be a workable way to
5 approach the issue, yes.

6 THE COURT: All right. Let me turn then to KV and
7 Mallinckrodt. I guess the issue is -- let's start with KV.
8 I'm sorry, we just handled KV. Mallinckrodt and Actavis. Let
9 me start then with Axinn Veltrop and Actavis. Is there
10 anything that you feel you need in terms of discovery on
11 inequitable conduct?

12 MR. LANDMON: Your Honor, on the inequitable conduct,
13 I'm not sure there is. We actually have no problem with there
14 being briefing on just the remanded issue based on just the
15 Endo record. That being said, we do think there's other
16 invalidity issues that we think are equally as important and
17 equally as dispositive in this case.

18 THE COURT: Hold on just a second.

19 MR. LANDMON: Sure.

20 (Pause)

21 THE COURT: Yes, sir.

22 MR. LANDMON: As I was saying, there are issues that
23 we believe are equally as dispositive as to the validity of the
24 patents. Mr. Sweeney and others have mentioned obviousness;
25 that's certainly one ground. Another ground with respect to at

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1 least the '042 patent, which is, by the way, the only patent at
2 issue with respect to Actavis, is whether the patent is invalid
3 for double-patenting.

4 And your Honor, our position is that we don't want
5 discovery to be stopped while the remanded issues are being
6 dealt with, and then come back where we are three, six months
7 down the road, and then have to start again at square one.

8 I don't know at this point whether we actually need
9 any further discovery on the other invalidity issues. What we
10 do need, we need obviously the documents and deposition
11 transcripts from the Purdue case. I mean if that was produced
12 to us sometime within the next few weeks, I think we would then
13 have a very good idea whether we need very targeted, limited
14 depositions, if any. And I do think we'd be in a position
15 really within the next few months to submit dispositive motions
16 on both the obviousness and double-patenting issues.

17 As to Purdue's concerns about they need discovery from
18 us, while I agree they may be entitled to some discovery from
19 us, the issue of obviousness and whether the patents were
20 obvious, are largely documents and issues that are in Purdue's
21 control documents, they are fully aware of. And while they may
22 need to depose one or two of our guys or be entitled to that, I
23 believe it's certainly something that can be accomplished in a
24 very short period of time.

25 And just kind of lastly, which I know is an issue
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1 addressed in our letter, with the HatchWaxman overlay that
2 commands the parties to expedite the case, we bid to stay all
3 discovery and then we need to start this over again three to
4 six months down the road; that it's both a prejudice to us and
5 nonconsistent with the HatchWaxman mandate.

6 THE COURT: All right. Thank you.

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7 MR. LANDMON: Thank you.
 8 THE COURT: Mr. Moore.
 9 MR. MOORE: Yes, your Honor. Just to give you our
 10 position on what's been said so far, we have carefully reviewed
 11 the trial transcript in the Endo case, post-trial briefs, the
 12 field briefs, and the briefs that were filed by Boehringer and
 13 Impax in the MDL ending last March. And Mallinckrodt flatly
 14 disagrees with Purdue that the additional issues raised by
 15 Boehringer and Impax in March were not part of the Endo record.
 16 And if I recall your Honor's opinion correctly, at one
 17 point there was a footnote in your opinion to the effect that
 18 the Court finds it unnecessary to rule on the additional
 19 allegations of misconduct put forward by Endo.

20 So it is entirely incorrect in Mallinckrodt's view to
 21 say that the sole issue that was tried in Mallinckrodt was --
 22

THE COURT: In Israel.

23 MR. MOORE: Pardon me. Trying to keep my parties
 24 straight at the start of the case. Entirely incorrect to say
 25 that Endo did not assert -- just simply asserted a single issue

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 1 and not a panoply of issues.
 2 THE COURT: I don't think that's a conceptual issue
 3 that presents difficulty for our structure. Here you're saying
 4 that their position that there are things being briefed on
 5 remand that weren't raised in Endo is wrong. It may be right,
 6 it may be wrong, but I don't think that changes our analysis,
 7 does it?

8 MR. MOORE: No, it doesn't.
 9 THE COURT: Okay.

10 MR. MOORE: It does, however, frame our perspective on
 11 the case. And from what we have been able to find from public
 12 sources, we find new acts of inequitable conduct by Purdue that
 13 were not asserted by Endo and not the subject of litigation.
 14 And Mallinckrodt flatly wants discovery on those additional new
 15 acts.

16 THE COURT: Right. But what are those?
 17 MR. MOORE: All right, sir. They are two. You may
 18 recall that the principal argument for patentability that
 19 Purdue made was that it had surprisingly been found that
 20 controlled-release oxycodone acceptably controls pain in the
 21 fourth oral dosage range in 90 percent of patients. That was
 22 the benefit of this invention.

23 Purdue set that benefit against the prior art in the
 24 following fashion: Purdue said in each of its patent
 25 applications, and over and over again, that surveys suggest

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 1 that other opiate analgesics, in the plural, required eightfold
 2 dosage range to control pain in 90 percent of patients.
 3 Testimony in Endo from the inventor Kaiko was that his insight
 4 was based upon his experience with morphine, and his review of
 5 records at Purdue concerning MS Contin. There has not been one
 6 word of testimony about any survey of any other opiate
 7 analgesic. And Mallinckrodt wants discovery on that precise
 8 question.

9 Second. Mallinckrodt has reason to believe that with
 10 respect to the purported survey of MS Contin, Purdue withheld
 11 from the patent office prior art references that contradicted

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12 the results of that purported survey. And this is in our
 13 affirmative defense. And our answer in the affirmative defense
 14 we filed about three weeks ago.

15 THE COURT: And you have the prior art references
 16 listed there?

17 MR. MOORE: No, your Honor, we do not.

18 THE COURT: Okay. Do you want to say what they are?

19 MR. MOORE: I do not have them in front of my brain
 20 this afternoon, sir, but can provide them.

21 THE COURT: All right. Let them know.

22 MR. MOORE: Now, on discovery. Well, first of all, we
 23 agree with Mr. Sweeney that what the Court has right at the top
 24 of its list is an unenforceability. And that will be different
 25 from invalidity.

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1 THE COURT: All right. I think you've convinced me of
 2 that, Mr. Sweeney has convinced me of that, Mr. Goldman has
 3 convinced me of that. I think I see that as a separation now,
 4 which I didn't before, of invalidity from unenforceability; and
 5 unenforceability resolving itself into an inequitable conduct
 6 issue. So what I'm seeing now is focusing on that inequitable
 7 conduct and not getting into discovery issues on obviousness
 8 and invalidity.

9 MR. MOORE: Here is Mallinckrodt's thinking on the
 10 subject. That Purdue immediately produce to the defendants the
 11 depositions and deposition exhibits for the inventors, for the
 12 attorneys, in-house and outside, involved in drafting the
 13 prosecution of the application, and anyone else involved in the
 14 drafting the prosecution of the application. There is no good
 15 reason why, given the routine electronic storage of deposition
 16 transcripts these days, that couldn't be done in a week.

17 Then we would have a limited period to conduct
 18 additional discovery devoted to the new matter that we have
 19 identified with respect to inequitable conduct. We would get
 20 to the end of that limited period, and Mallinckrodt would
 21 propose 90 days after production of the documents that I've
 22 described.

23 Then Mallinckrodt would try to decide for itself
 24 whether it can present new information on the basis of the
 25 written record, or if credibility is an issue, whether there

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1 ought to be a very short hearing. And then we would proceed
 2 with briefing.

3 With respect to the other issues of invalidity,
 4 Mallinckrodt's thought has been that it's a bit academic;
 5 because the likelihood is 95 percent of discovery that the
 6 defendants can reasonably expect to get from Purdue has already
 7 been done by competent counsel in two prior cases. If we have
 8 a dump, as the judge puts it, that is going to go a very long
 9 way for practical purposes to ending the necessity for
 10 discovery on the defendant's side. But that can go on a
 11 separate track.

12 THE COURT: Well, I think where we're left is a more
 13 narrow focus than you had originally contemplated, but it may
 14 be the most logical way to go. That is, to have limited
 15 discovery only on new inequitable conduct arguments, which I
 16 take it are only being raised by Mallinckrodt, is that right,

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17 KV and Actavis?
 18 MR. SWEENEY: Your Honor, I think that's right, but
 19 I'm not quite sure exactly what Mr. Goldman means when he says
 20 "new."
 21 THE COURT: Well, "new" is anything that's not in the
 22 Endo record.
 23 MR. SWEENEY: Okay. That's fine. We're comfortable
 24 with that.
 25 THE COURT: Mr. Goldman, did you want to say
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 something?
 1 MR. GOLDMAN: Well, only that based on the past
 2 briefing, newness seems to be in the eyes of the beholder.
 3 THE COURT: I understand. But it's Purdue actually
 4 who wanted to supplement the Endo record, if I remember
 5 correctly.
 6 MR. GOLDMAN: That is correct. Because we believed
 7 that we were facing arguments that had not been made before,
 8 arguments that we had not had an opportunity to respond to at
 9 the Endo trial. And so long as we have the opportunity to at
 10 least ask for that relief again --
 11 THE COURT: Well, if you think you've been aggrieved
 12 by their making arguments that were not part of the Endo trial,
 13 then you can make that request.
 14 MR. GOLDMAN: All right. Fine. I don't want to be
 15 cut off from challenging that by an undertaking today that
 16 we're going forward with one thing and not another.
 17 THE COURT: All right. No problem there.
 18 MR. GOLDMAN: Thank you, your Honor.
 19 THE COURT: Actavis, I think you've already indicated
 20 that there's no separate inequitable conduct issues that you're
 21 raising.
 22 MR. LANDMON: That is correct. We don't intend to do
 23 that. I did have one question, from at least where I assume I
 24 think you're heading.
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 Once we get all this, as it's described, a document dump, I mean I think from our perspective we will largely be in a position that we will at least think that there are invalidity issues where we believe there will be no factual disputes, no material facts at issue, and we would at least like the ability to not have to wait until after this first proceeding is over to submit a summary judgment motion based on those issues that obviously Purdue could then respond to you by pointing out where they believe there may be factual issues. That to us would show that going forward then, to the extent they say there are factual issues, there has been this limited discovery that needs to take place.
 THE COURT: Do that again. I thought where you were going with that was you want to move for summary judgment on invalidity, while the discovery on inequitable conduct goes forward. But then I'm not sure that's where you ended up.
 MR. LANDMON: I'm sorry. Yes. I mean that's what we'd like to be able to do if, once we get the depositions and everything from the previous cases, shows us that there are no material facts at issue with respect to the invalidity arguments we have made. And I guess I was pointing out that I

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22 think that is an efficient procedure; because to the extent
 23 that through the 56(f) procedure Purdue believes there are
 24 actually material facts at issue, we can then focus whatever
 25 continued discovery there is later on those narrow issues. And

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 1 to the extent that there aren't any factual issues --
 2 THE COURT: No, I understand. Mr. Goldman?

3 Mr. Sweeney?

4 MR. GOLDMAN: Your Honor, I believe if we're going to
 5 get into the issues of invalidity, and in particular the issue
 6 of obviousness or obviousness-type double-patenting, which is
 7 where counsel indicated they were going, we're going to be in a
 8 situation where Purdue is going to want to take more discovery
 9 from the defendants than counsel for the defendants is now
 10 contemplating. Not for purposes of delay, but because we think
 11 that it's relevant to evidence and relevant to the question of
 12 the obviousness analysis, particularly as informed by the
 13 recent law.

14 And so if we're heading down that road, I think we're
 15 heading into the place where your Honor didn't want to be; that
 16 is, we're going to begin to multiply these issues rather than
 17 simplify them.

18 So we'll obviously do whatever the Court wants to do.
 19 We're prepared to start discovery on all issues. But if we're
 20 going to just start to slice and dice it --

21 THE COURT: I understand your position. Yes, sir.

22 MR. SWEENEY: We would prefer to deal with inequitable
 23 conduct, the remanded issues, on the Endo record, and leave the
 24 two-way discovery of invalidity --

25 THE COURT: I think that's probably the best way to go

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 1 at this point, because it enables me to focus on what the
 2 Federal Circuit wanted me to focus on; and it enables me to
 3 keep a very short leash on discovery. To the extent that I'm
 4 starting to allow discovery on invalidity, I'm going to have
 5 not as good control over a short period of time; or put another
 6 way, I'm going to have to allow more time for discovery.

7 So we'll go forward on unenforceability, and by that I
 8 mean inequitable conduct. We're going to stay the antitrust
 9 counterclaims, and we're not going to proceed at this time on
 10 invalidity issues, we're not going to proceed on infringement
 11 issues. Parties should get together and draft an order for my
 12 signature on that.

13 Now, let's talk timing. I want to have this in my
 14 hands by the beginning of October. And I've got to leave some
 15 period of time for debate as to whether a hearing is needed.
 16 That may be obviated by the discovery, but at least I've got to
 17 build in that time.

18 Purdue, I don't think you should have any problem with
 19 Mallinckrodt's request for production of the depositions and
 20 deposition exhibits from the inventors, the attorneys, and the
 21 prosecution file.

22 MR. GOLDMAN: Once we're able to agree on a protective
 23 order, I believe that's correct. My understanding from
 24 Mr. Normile is that in the Mallinckrodt case the parties are
 25 more or less agreed on the terms of a protective order and can

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 2 finalize that and get that to your Honor for signature.
 3 THE COURT: You mean "the parties" meaning you and
 4 Mallinckrodt?
 5 MR. GOLDMAN: Meaning Purdue and Mallinckrodt.
 6 MR. NORMILE: Mr. Moore and I have negotiated for a
 7 protective order which I believe is ready for submission --
 8 MR. MOORE: Next week.
 9 MR. NORMILE: -- early next week, your Honor.
 10 THE COURT: Obviously I want protective orders in
 11 place, but there shouldn't be any problems.
 12 MR. GOLDMAN: Right. In KV and Actavis we had sort of
 13 a three-corner negotiation going on and we're not quite there
 14 yet. I mean hopefully we can wrap that up in the next week or
 15 so or write to your Honor and explain why we can't.
 16 THE COURT: Okay. In the long history of this
 17 litigation, I don't think there's ever been an issue with the
 18 protective order. Let's focus on that. This discussion should
 19 probably help you focus on that. Let's not let it be a
 20 barrier.
 21 Let's get a protective order in place so everybody's
 22 trade secrets and confidential information is protected and
 23 used only in connection with this litigation.
 24 Next item. I think that's fairly -- I understand the
 25 need for it, I'm just indicating --
 MR. GOLDMAN: We're going to move past that.

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 2 THE COURT: Okay.
 3 MR. GOLDMAN: Now, in terms of documents, looking at
 4 what was done in, I guess it was, Impax, this litigation has
 5 been going on long enough that at least when it began, a lot of
 6 things weren't kept electronically. And so we have most, but
 7 not all, of the documents that were put on CDs in connection
 8 with Impax. And we can certainly make those available within a
 9 couple of days after the entry of a protective order, once we
 reach agreement.
 10 So as to the remaining documents, I think it will
 11 probably take us -- and what those are, the remaining documents
 12 are some court filings and things. They are not the deposition
 13 exhibits and things that people have been talking about.
 14 As to the remaining documents, I'd like to think we
 15 could get those done over the next four weeks. But certainly
 16 if we can get a protective order done next week, I believe we
 17 can certainly get the electronic copies of things to the
 18 defendants sometime in the week of the 23rd. We have to
 19 duplicate the CDs, we just have to make sure we have
 20 everything.
 21 There were also some third-party issues involving
 22 approaching Endo and then Boehringer for permission to make
 23 some of those materials available. And we have to deal with
 24 those. That was a problem the last time. I'd like to think --
 25 we've produced some things to Actavis already, and I'm pretty

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 2 sure we can move forward expeditiously on them.
 THE COURT: All right. I think your answer to my
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3 question is you don't have a problem with it; there are just
4 some mechanical issues that you need to resolve.

5 MR. GOLDMAN: Yes. My point simply was that we can't
6 do it tomorrow, but we can certainly do it expeditiously.

7 THE COURT: I'll put a finer point on that in just a
8 moment. But okay, I understand that.

9 MR. GOLDMAN: Thank you.

10 THE COURT: Now, if we're talking about the beginning
11 of October, for me to have these either in brief form or have
12 the discussion about a hearing, we're not going to have 90 days
13 for discovery. Really what we're going to have is 60 days of
14 discovery, probably not even that.

15 All right. Let's have production of all of those
16 documents, of all of this, by August 10th. If there's any
17 holdup on the protective order, just submit it to me. We're
18 going to have discovery. Are there expert reports needed on
19 inequitable conduct issues? I wouldn't think so.

20 MR. MOORE: Your Honor, we proposed the schedule, and
21 this schedule is based on the explicit assumption that there
22 will be no place for expert reports.

23 THE COURT: I don't think that inequitable conduct
24 lends itself to that. If anybody wants to say otherwise, they
25 can.

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1 MR. MOORE: I will tell you at the moment, not
2 knowing what's in the very restricted, and I would point out,
3 very restricted documents that we're asking for in connection
4 with inequitable conduct, without knowing that, we don't
5 contemplate very much additional discovery, I have to be clear
6 about that.

7 THE COURT: All right.

8 MR. MOORE: At the moment, I see three depositions.
9 But again, I'm looking at a black box; so I can't take a firm
10 position on how much we're going to require.

11 THE COURT: Well, given that, what I'd like to do, and
12 I appreciate your directness, I'd like to cut you down then to
13 45 days, with an ability to come back to me, because if you're
14 talking three depositions, and if you have a good grasp of the
15 Endo file, you're pretty far along, sir.

16 MR. MOORE: Well, your Honor, I will add only this:
17 Purdue was already listed in one filing in the MDL. The extent
18 of the depositions -- of most of the individuals I've
19 described, Dr. Kaiko suffered apparently through 11 days of
20 depositions.

21 THE COURT: Don't forget his time on the stand.

22 MR. MOORE: We're looking at a lot of transcript that
23 we haven't seen before. And we can put our best efforts on it,
24 but to get that, which counsel has agreed to produce in, what,
25 a month, to get that, read it --

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1 THE COURT: What date did I put on it?

2 MR. MOORE: It's going to be tough.

3 MR. NORMILE: August 10th.

4 THE COURT: The 10th. So it's essentially marked,
5 that's right. Well, for example, the Kaiko depositions, you
6 don't have to wait a month to produce those. I presume those
7 are in a dusty box somewhere.

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8 MR. GOLDMAN: I wasn't planning to wait until the last
9 day, your Honor.

10 THE COURT: Okay.

11 MR. GOLDMAN: I believe we have those in electronic
12 form. Once we have a protective order, we'll begin to roll
13 those things out. And we'll work with counsel; if they want to
14 prioritize things, we'll try to work with them to make that
15 happen.

16 THE COURT: All right. Let's do it. Then the last
17 day for fact discovery is September 14. We'll have a pretrial
18 conference on -- and then essentially, I'm not going to
19 schedule the briefing right now, but essentially we'll exchange
20 briefs over the following two weeks, three weeks, is what we're
21 looking at.

22 So as you do this discovery, you should be thinking
23 about what that briefing is going to look like, and you
24 essentially have briefs that have already been put in on remand
25 in other cases. So the briefing can be quite short. I'll

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1 bring you in for a status conference, just to make sure that
2 everything is moving the pace. Can we do it on August 23rd or
3 are people away? It's the end of August. Is that doable?

4 MR. GOLDMAN: I'll be out of the country that week,
5 your Honor.

6 THE COURT: Do you feel comfortable for somebody else
7 to appear for a status conference?

8 MR. GOLDMAN: Yes. Thank you.

9 THE COURT: I thought that would be the answer.
10 August 23rd at 10 a.m. And if anybody wants to move that up,
11 meaning earlier, because everybody's away that following week,
12 just let me know. The idea is just to make sure things are
13 moving appropriately.

14 MR. SWEENEY: Your Honor, do I understand that at that
15 pretrial conference on August 23, you're going to -- or status
16 conference, you're going to set the briefing schedule?

17 THE COURT: Yeah. That's what I'd like to do. What I
18 want is everybody to come in and tell me discovery went very
19 smoothly; there are no problems; in fact, we're ready to go
20 now. But if we're not, I'll handle those issues and set a
21 briefing schedule, exactly, so that I could have this in my
22 hands in the beginning of October. And I want to know what the
23 parties feel about a hearing, and I'll handle that at the
24 August 23rd date, as well. August 23rd at 10 a.m. just for
25 status for everybody.

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1 Is there anything else I need to handle?
2 There are two other issues in the Rule 26,
3 Mr. Goldman. One had to do with the electronic format; I take
4 it that's nothing I need to decide now, whether it could be in
5 need of characters or tip form. Are you generally handling
6 that?

7 MR. GOLDMAN: Yes, I do. There's nothing to decide
8 there.

9 THE COURT: And I agree. There's one other issue,
10 which I forget what it was --

11 MR. GOLDMAN: It probably had to do with how one
12 counts the parties for purposes of discovery limits. And for

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13 this period, I don't believe that's an issue.
14 THE COURT: I think that's right. All right. Yes,
15 sir.
16 MR. MOORE: One last question. Mr. Normile had been
17 going through a series of discussions on plans with our --
18 THE COURT: I'm sorry, a little louder, sir.
19 MR. MOORE: I apologize, your Honor. We've been
20 having ongoing discussions about Rule 26(f), volunteering
21 disclosures and so on. We haven't actually exchanged any paper
22 yet. And I don't know what your Honor's inclinations are with
23 respect to that exercise. Should we continue with it or stop
24 it and concentrate on this inequitable conduct issue?
25 THE COURT: Sir?

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1 MR. NORMILE: Well, if I understand correctly, we were
2 talking about wide-open discovery during our Rule 26(f)
3 discussions, not the narrow focus that your Honor has just
4 articulated.

5 MR. MOORE: That's correct, yeah.
6 MR. NORMILE: It would be my understanding we'd stop
7 that and focus on this.
8 THE COURT: All right. I don't have a problem with
9 that. I do think the way to handle it and to take care of the
10 Federal Circuit's remand is to do inequitable conduct. And I
11 think whatever the ruling on that, it will help structure the
12 remainder of this case -- of these cases and the MDL.

13 MR. MOORE: There was one last thing I wanted just to
14 briefly mention, Judge. And I have been struggling with the
15 exact procedural posture we find ourselves in. None of the
16 defendants were parties to the Endo trial obviously.

17 It seems to me that we are all agreed that the Endo
18 record is going to provide probably the major vehicle,
19 certainly in terms of volume, for decision in this inequitable
20 conduct issue.

21 THE COURT: Sir, that was greatly mooted throughout
22 that case. I would think it's essentially what inequitable
23 conduct is going to go forward on. I'm not bowled over by the
24 articulation of the new allegations of misconduct, but I don't
25 have any substance yet behind them, so I'll wait for that. But

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1 I think you're quite right, it's going to be Endo.
2 MR. MOORE: While we have been struggling a bit to
3 characterize exactly where we are. And just to get our view of
4 the procedural posture on the table, it appears that where we
5 are headed is essentially a final adjudication on the issue of
6 inequitable conduct by agreement of the parties on the basis of
7 a submission of a written record, in effect, in the Endo, plus
8 supplementation of the sort that we've discussed today.

9 THE COURT: And legal arguments, and presumably oral
10 presentation of legal argument.

11 MR. MOORE: Correct. It's kind of a trial on a
12 written record, that's where we are, or the functional
13 equivalent of it, with a final adjudication with the
14 inequitable conduct issue all the way at the end.

15 THE COURT: I think that's a fair characterization.
16 Does anyone disagree with that characterization? I think
17 that's exactly where we are. And I think we can do that based

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18 on the fullness of the Endo record. And if there's something
19 else you come up with in the discovery -- but if you're coming
20 up dry, don't prolong everybody's agony. We'll move this case
21 forward.

22 MR. MOORE: Your Honor, if the answers to our
23 questions are in the depositions that are already taken, we'll
24 come and tell you that.

25 THE COURT: Great. And then what that will do is it
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2 will give everybody additional time for briefing. So let
3 everybody know that, then we can build in more time for
4 briefing.

5 All right. Thank you. I appreciate everyone's
attention.

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